MEDDAC/DENTAC Regulation 40-35

Medical Services

The Patient Safety Program

Headquarters
U.S. Army Medical Department Activity
Fort George G. Meade
2480 Llewellyn Avenue
Fort George G. Meade, MD 20755-5800
12 August 2003

Unclassified

SUMMARY of CHANGE

MEDDAC/DENTAC REG 40-35
The Patient Safety Program

This is the initial publication of this regulation.

Department of the Army
Headquarters
United States Army Medical Department Activity
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Regulation 40-35

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The Patient Safety Program

FOR THE COMMANDER:

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Official:

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History. This is the initial publication of this regulation.

Summary. This regulation establishes policies and procedures for administering the Patient Safety Program within the MEDDAC.

Applicability. This regulation applies to Headquarters, U.S. Army Medical Department Activity, Fort George G. Meade (MEDDAC) (that is, Kimbrough Ambulatory Care Center (KACC), all subordinate U.S. Army health clinics (USAHCs), Dental Clinic No. 3 of the U.S. Army Dental Activity (DENTAC), Fort George G. Meade. This regulation also to the OHESS Satellite Clinic located in KACC, and to all contract employees and Red Cross volunteers employed in any of the MEDDAC's medical treatment facilities (MTFs).

Supplementation. Supplementation of this regulation is prohibited.

Proponent. The proponent of this regulation is the Patient Safety Manager.

Suggested improvements. Users of this publication are invited to send comments and suggested improvements, by memorandum, directly to the Commander, U.S. Army Medical Department Activity, ATTN: MCXR-QM, Fort George G. Meade, MD 20755-5800, or to the MEDDAC's Command Editor by fax to (301) 677-8088 or e-mail to john.schneider@na.amedd.army.mil.

Distribution. Distribution of this publication is by electronic medium only.

Contents (Listed by paragraph and page number)

Contents–continued

Table List

Appendixes

Glossary

Chapter I
Introduction

1-1. Purpose
This regulation prescribes policies, procedures and responsibilities for administration of the Patient Safety Program within the MEDDAC, to include the OHESS Satellite Clinic, and Dental Clinic No. 3, a DENTAC asset located within KACC. (Hereafter, the phrase "the command" will be used to represent the entire MEDDAC and Dental Clinic No. 3.)

1-2. References
Required and related publications are listed in appendix A.

1-3. Explanation of abbreviations and terms
Abbreviations and special terms used in this regulation are explained in the glossary.

1-4. How this regulation applies to the outlying clinics
Much of this regulation is written in such a way as to address procedures at KACC. To address the various procedures within this regulation as they variously apply to each and every MTF within the MEDDAC would result in a huge and unwieldy directive. Therefore, it has been deemed best, for the most part throughout this regulation, to address procedures as they apply to KACC, and for the commanders and chiefs of the several outlying USAHCs to develop similar procedures for their own facilities.

Chapter 2
Responsibilities

2-1. The MEDDAC Commander
The MEDDAC Commander will—

a. Ensure implementation and compliance with the Army Medical Department's (AMEDD's) Patient Safety (PS) policy as defined in U.S. Army Medical Command (MEDCOM) Regulation 40-41.

b. Promote a culture that emphasizes cooperation and communication, encourages reporting of medical errors, focuses on error prevention rather than punishment, and improves medical systems and processes to overcome preventable errors.

c. Designate an individual as the Patient Safety Manager (PSM) to direct the command-wide Patient Safety Program (PSP).

d. Allocate the resources required to sustain a comprehensive, integrated PSP according to the provisions of this regulation.

e. Promote strategies to encourage and facilitate staff identification and reporting of close calls/near misses and actual PS events.

f. Designate membership of the Patient Safety Committee, to serve as the MEDDAC's Patient Safety Team (PST) and be responsible for support and oversight of all PS activities.

g. Ensure all staff are educated on AMEDD PSP components and roles and responsibilities, as well as effective communication, coordination, and teamwork techniques, as applicable.

h. Facilitate the education of MEDDAC MTF beneficiaries regarding their roles and responsibilities as partners in the health care process, to include identification of PS-related issues.

i. Designate a Root Cause Analysis Team (RCAT) facilitator and ensure the facilitator receives proper formal training through MEDCOM resources.

2-2. The Deputy Commander for Clinical Services (DCCS)

The DCCS will—

a. Oversee the activities of the PSP and serve as chairperson of the interdisciplinary MTF PST, as designated in MEDDAC/DENTAC/VS Regulation 15-1.

b. Ensure that PSP activities are implemented, monitored and evaluated for effectiveness in accordance with (IAW) the provisions of this regulation.

c. Support an organizational culture that emphasizes cooperation and communication, encourages reporting of potential and actual PS events, focuses on error prevention rather than punishment, and improves medical systems and processes to overcome preventable errors.

d. Facilitate orientation and ongoing education of all staff regarding their roles and responsibilities.

e. Ensure that a qualified health care professional informs the patient and/or family members, as stated below in paragraph 4-7c, when a PS event results in an unanticipated outcome of care.

f. Promote support and assistance to any staff member involved in a sentinel event.

2-3. The Deputy Commander for Nursing (DCN) and the Deputy Commander for Administration (DCA)

The DCN or DCA will, in the absence or unavailability of the DCCS, ensure that a qualified health care professional informs the patient and/or family members when a PS event results in an unanticipated outcome of care, IAW paragraph 4-7c, below.

2-4. Supervisors

Within their respective activities, supervisors will—

a. Ensure PSP activities are implemented, monitored and evaluated for effectiveness, and actively participate in these processes.

b. Support a culture that emphasizes cooperation and communication, encourages reporting of potential and actual PS events, focuses on error prevention rather than punishment, and improves medical systems and processes to overcome preventable errors.

c. Facilitate orientation and ongoing education of all staff regarding their roles and responsibilities in the PSP.

d. Actively participate in and facilitate the timely acknowledgement of reported PS events and feedback to individuals (staff, patients, family members and visitors) who report PS events.

e. Facilitate coordination, integration, and implementation of inter- and intra-departmental PS initiatives.

f. Propose recommendations for improving PS to the PSM and/or the PST.

g. Promote support and assistance to staff members involved in sentinel events.

h. Designate a qualified health care professional to inform the patient or family members when a PS event results in an unanticipated outcome of care, IAW paragraph 4-7c, below.

i. Ensure that staff members educate patients and family members on their roles and responsibilities relative to the safe delivery of health care.

2-5. The Chief, Logistics Division and the Chief, Pharmacy Service

Chiefs, Logistics Division and Chief, Pharmacy Service will, in addition to the responsibilities listed in paragraph 2-4, above, for supervisors, facilitate notification of the PSM and appropriate department, service and division chiefs regarding all product liability complaints and recalls.

2-6. The PSM

The PSM will—

a. Plan, develop and direct the MEDDAC PSP IAW Joint Commission on Accreditation of Healthcare Organizations (JCAHO) standards and the AMEDD PSP.

b. Provide expertise and guidance to staff members in the areas of risk assessment, prospective analyses, aggregate analyses, risk cause analyses, and the development and evaluation of action plans.

c. Serve as the liaison to the MEDCOM Patient Safety Center (PSC).

d. Coordinate, facilitate, and/or educate all MEDDAC personnel concerning their roles and responsibilities in the PSP, to include reporting of all PS events, participating in MEDDAC PS activities, and educating patients and families regarding all aspects of the safe delivery of health care.

e. Ensure that both MEDDAC staff and beneficiaries are surveyed, according to current Department of Defense (DoD) guidance, to determine their perceptions of PS within their health care organizations and maintain aggregate data of surveys to determine educational and perceptual deficiencies. The MEDCOM PSC will periodically provide the survey tool and instructions for its use.

f. Implement a process to receive and centrally manage all PS event reports from clinical and administrative staff, and/or patients and families, in coordination with the Risk Manager.

g. Evaluate each PS event report in conjunction with the Risk Manager and, based on the assigned safety assessment code (SAC), determine the appropriate level of review or analysis required.

h. Oversee the investigation of all sentinel events to ensure coordination of all data collection activities, completion of a thorough and credible route cause analysis (RCA), development of an action plan, and required reporting through channels to the appropriate agency or agencies.

i. Acknowledge receipt of PS reports and provide timely feedback to staff members who submit them, and/or plans for process and system improvements, in conjunction with the Risk Manager.

j. Ensure that PS action plans are implemented, evaluated for effectiveness, and communicated internally and, if required, to appropriate external organizational entities.

k. Maintain the PS database and submit information and reports regarding PS events, RCAs, action plans, and aggregate data to the PST and MEDCOM PSC.

l. Review, aggregate, and analyze reports of all close calls, adverse events, and sentinel events, to include written findings and recommendations for improvements in systems and processes, to reduce the frequency and severity of patient harm.

m. Serve as a voting member of the PST and provide the PST, as well as all levels of staff, information regarding MTF, corporate, and nationwide PS alerts, updates, and initiatives.

n. Present opportunities for improvement related to organizational risk assessments, with recommendations for identified risks, implementation plans, and follow up activities to the PST and MEDCOM PSC for action.

o. Oversee the education of the beneficiary population regarding the role of patients and family members in the identification of PS-related issues.

p. Ensure effective feedback to appropriate personnel on lessons learned, and process and system improvements that have been or will be initiated.

q. Ensure PS events due to environmental factors are addressed through the Safety and Environment of Care Committee.

2-7. The MTF safety officer

The MTF safety officer will serve as a voting member on the PST and serve as an active PST participant IAW MEDDAC/DENTAC/VS Reg 15-1, paragraph 3-10.

2-8. The MTF staff

The MTF staff will—

a. Understand and take responsibility for their own roles in the PSP.

b. Actively participate in creating a safe environment for themselves, other members of the staff, patients, families and visitors by meeting organizational and professional standards, following identified best and safe practices, and by proactively mitigating unsafe conditions and situations.

c. Complete organization and unit-based orientation and participate in ongoing education, IAW the MTF's policy, related to the AMEDD PSP and all MTF PS activities.

d. Voluntarily report all close calls/near misses, adverse events, and sentinel events.

e. Initiate immediate steps to ensure patient and staff safety and secure any supplies and equipment that may have precipitated a PS event in order to prevent and/or mitigate future patient harm. If an event is caused by or exacerbated by a supply or equipment problem, initiate a medical materiel complaint IAW AR 40-61. Submission of this complaint also satisfies the reporting requirement of the Safe Medical Devices Act of 1990.

f. Educate patients and families regarding their roles and responsibilities to facilitate the safe delivery of health care.

g. Remain informed of recommended successful best and safe practices and safety alerts.

Chapter 3
Description, Goal, and Focuses of the PSP

3-1. Description of the PSP

a. Patient safety involves a variety of clinical and administrative activities that health care organizations undertake to identify, evaluate and reduce the potential for harm to beneficiaries and to improve the quality of health care. Effective medical and health care error reduction requires an integrated approach and a supportive environment in which patients, their families, organization staff, and leaders can identify, manage and learn from actual and potential risks.

b. A successful PSP facilitates a non-punitive, interdisciplinary approach to decrease unanticipated adverse health care outcomes. The organizational focus is on continued learning about risks and mitigation strategies and reengineering systems and processes to reduce the chance of human error. The AMEDD and the MEDDAC foster and support an organizational environment that recognizes and acknowledges potential risks to PS and the occurrence of medical and health care errors. The PSP encourages medical error reporting in order to identify system or process

failures and to enhance improvement strategies.

3-2. The goal of the PSP

The goal of the PSP is to reduce the chance that adverse effects of human error will harm patients.

3-3. Focuses of the PSP

a. The PSP focuses on system and process design rather than on the individual involved in a given PS-related mishap.

b. For all potentially compensable events (PCE), current regulatory guidance in AR 40-68 requires that an investigation be conducted to determine the cause(s) of the adverse event. In all paid medical malpractice claims, current legal statutes dictate that the professional practice of the significantly involved provider or professional will be reviewed to determine if the standard of care (SOC) was met. This risk management (RM) review and reporting process, involving the National Practitioner Data Bank and other regulatory agencies, is likewise delineated in AR 40-68. While the PSP and RM processes are both protected under 10 USC 1102, each has its unique intent and focus.

c. A PS event that causes no patient harm does not require a SOC determination. However, any PS event that results in patient harm is a PCE. The Risk Manager will be notified of all PCEs and these will be managed according to the RM guidance in AR 40-68 and MEDDAC Reg 40-32. Given the results of the RM investigation of the event, a SOC determination may be required. It may be appropriate and expedient to conduct the PS activities and SOC determination simultaneously, as separate but parallel activities. Competence-related information that arises through PS investigations will not be released outside the PSP except as noted in paragraphs d and e, below. The PSP will consider process and system issues, while the SOC determination reviews the individual's performance.

d. Although not a specific focus of the PSP, concerns about a specific provider's professional competence may arise. Competence relates directly to an individual and, as such, requires an evaluation of the provider's professional performance, not an evaluation of the health care system. Competence will be addressed through the organization's competence assessment, credentialing, and privileging processes. No individual competence-related information will be released outside the PSP, except as noted in paragraph e, below. If competency assessment processes are determined to require review and improvement, such recommendations by the PST may be appropriate.

e. The vast majority of errors are unintentional; disciplinary action will not be initiated against individuals involved in unintentional errors. Certain events, as listed below, do warrant investigation and may result in administrative, disciplinary, and/or legal action. Should any of the following be discovered in the course of a PS event evaluation, the Commander will be immediately informed of the circumstance:

(1) Criminal activity (such as rape, battery or assault and battery, and homicide).

(2) Intentional unsafe acts due to gross negligence or reckless behavior.

(3) Alleged patient abuse of any kind.

(4) Impairment due to medical or psychological conditions, including alcohol or other drug abuse.

(5) Trend in an individual toward repetition of the same error(s).

Chapter 4
The PST and its responsibilities

4-1. Organization of the PST

The Patient Safety Committee, which is multidisciplinary, also serves as the MEDDAC's PST. The membership of the Patient Safety Committee is listed in MEDDAC/DENTAC/VS Reg 15-1, chapter 3, and is subject to change. All PS-related processes and issues are integrated under this committee/ team.

4-2. PS organizational assessment

Patient safety encompasses complex, multidisciplinary processes. The MEDDAC will systematically assess its high-risk organizational systems and processes to identify and prioritize safety improvement requirements. High-risk services and areas include but are not limited to invasive and operative procedures, radiology, medication administration, and pharmacy (medication dispensing).

a. The PSP's organizational assessment facilitates the MEDDAC's evaluation of its current safety program and its various components as well as current policies and procedures. As a result of this evaluation, the PSP's improvement strategies can be appropriately prioritized.

b. The MEDDAC will perform an organizational PS assessment annually, according to its performance improvement priority schedule, using the measurement tool(s) provided by the MEDCOM PSC.

c. Other appropriate PS assessment activities may include reviewing external data reports to identify high risk areas for organizations of similar size and patient populations. External sources of information include, but are not limited to, JCAHO sentinel event report information, MEDCOM consolidated reports, and MEDMARX.

d. Annual PS assessment activities may identify more than one organizational high risk process improvement need. The PST will document and recommend high risk process improvement priorities to the Quality Improvement and Risk Management Committee, which will submit them to the Executive Committee for evaluation. The Executive Committee will select one high risk process for the PST to focus on, and ensure the PS Team completes a prospective analysis, utilizing Failure Mode Effects Analysis.

e. Any additional high risk processes that have been identified will be prioritized and included in the Quality Improvement and Risk Management Committee's annual performance improvement plan. Formal analyses and improvement strategies for these process improvements will be completed per availability of appropriate organizational resources. Clinical areas are expected to perform high risk assessments of their own areas and include those in their performance improvement activities.

4-3. Management of PS information

a. The focus of PS data collection and reporting in the AMEDD is to improve organizational systems and to provide the safest care possible to DoD beneficiaries.

b. To examine trends in reported events within the MEDDAC and across the AMEDD, the MEDDAC will, as a minimum, systematically collect MEDCOM-identified PS event core data elements.

c. Data trend analysis will include but not be limited to the following:

(1) Medication errors and falls.

(2) Equipment malfunctions.
(3) Events categorized by severity per SAC methodology.
(4) Preventive and corrective interventions implemented.

d. Customized ad hoc queries and reports will be developed as directed by the MEDCOM PSC's published schedule. These may be requested from the PSM by internal MTF or external DoD activities.

e. Detailed analysis of data using the query and reports capabilities, as developed by the MEDCOM PSC, will provide useful information to any level of management. This information will highlight the various contributing factors associated with PS events and facilitate decision-making regarding the specific process improvements required prevent recurrence.

4-4. PS event management

a. *Event identification*. A PS event is any incident that occurred (actual event) or almost occurred (close call/near miss), that caused or had the potential to cause harm to a patient. Identification and reporting of close calls and adverse events, including those that result from practitioner error, should be encouraged as an expectation of everyday practice. The three types of PS events include close calls/near misses, adverse events, and sentinel events.

(1) *Close call/near miss*. A close call is an event or situation that could have resulted in harm to a patient, but did not, either by chance or through timely intervention. The event was identified and resolved before reaching the patient. Such events have also been referred to as "near miss" incidents. Because close calls generally occur more frequently than actual adverse events, proactive analysis of close calls provide a tangible opportunity to improve the system without having to experience an actual adverse event. Leaders should emphasize the value of close calls and encourage and acknowledge staff for reporting these opportunities for improvement.

(2) *Adverse event*. An adverse event is an occurrence associated with the provision of health care or services that may or may not result in harm to the patient. Adverse events may be due to acts of commission or errors of omission. Incidents such as patient falls or improper administration of medications are also considered adverse events even if there is no harm or permanent effect on the patient.

(3) *Sentinel event*. A sentinel event is an unexpected occurrence involving death, serious physical or psychological injury, or the risk thereof. Serious injury specifically includes loss of limb or function. The phrase, "or the risk thereof," includes any process variation for which a recurrence would carry a significant chance of a serious adverse outcome. Such events are called "sentinel" because they signal the need for immediate investigation and proactive response on the part of the organization.

b. *Event documentation and internal reporting*. Preventing patient harm is *everyone's* responsibility, and reporting all potential and/or actual PS events is a performance expectation for all MEDDAC assigned staff. Anyone with knowledge of a PS event not only may, but *should* report it.

(1) *Immediate actions*.

(a) Upon identification of an actual PS event, the staff member will immediately perform necessary health care interventions to protect and support the patient's clinical condition. The patient's attending physician and other physicians, as appropriate, will be contacted as soon as possible to report the incident and to provide an update on the patient's current clinical status.

(b) As appropriate to the event, the staff member will initiate all physician-directed orders and take other necessary health care interventions to contain the risk to others and to preserve

event-related materials that may require further investigation. Examples of physical information preservation include preservation of intravenous (IV) tubing, and the fluids bag with a severe drug reaction from IV medication. An entire room or area may need to be immediately secured and/or locked to prevent the loss of valuable information. Preservation of information also includes documenting the facts regarding the event in the patient's medical record according to organizational policy and procedure.

(c) If the PS event involves serious physical or psychological injury, unexpected death, or qualifies as a sentinel event that is subject to review by JCAHO, the appropriate department or service chief and the nursing supervisor will be notified immediately. If such PS events occur after hours, the administrative officer of the day will be notified immediately. Individuals notified will ensure proper notification of designated members of the MTF senior leadership.

(2) *Documentation and internal reporting*. Any individual in any department who identifies a potential event (that is, a close call) may initiate a "Near Miss" Report. There are three versions of the "Near Miss" Report. At KACC and Barquist USAHC, use MEDDAC Form 756. At Dunham USAHC, use MEDDAC Form 761, and at Kirk USAHC, use MEDDAC Form 767. For an actual PS event, the reporting individual will immediately notify his or her supervisor, then initiate an incident report on Department of the Army (DA) Form 4106 (Quality Assurance/Risk Management Document). This report will contain concise, factual, objective and complete details about the event. While explanation of the event is appropriate to include precipitating circumstances or reasons, speculation about factors that contributed to the event should be avoided.

(a) Incident reports will be forwarded to the staff member's supervisor within 24 hours of discovery of the event, or on the first duty day following a weekend or holiday. The supervisor will review the document, add any additional relevant information, and forward it to the Quality Management Office within 24 hours of receipt.

(b) The MTF PSM or designee will review all incident reports and assign a SAC IAW appendix B. In addition, the PSM and RM will determine what specific actions are necessary to further evaluate SAC 2 events. If the PS event is a SAC 3, the PSM or RM will immediately notify the Commander and an RCAT will be chartered. The PSM will also enter the information from the incident report into the MTF PS database. The flow of information and review and analysis processes for DA Form 4106 are outlined in MEDDAC Reg 40-32.

(c) SAC scores will be reviewed and agreed upon by consensus of the PSM and RM. All incidents and unusual occurrences identified as potentially compensable events will be referred to the appropriate risk management and peer review processes for investigation.

(d) If a PS event is an intentional unsafe act that results from gross negligence or possible criminal activity, the event will be reported to the appropriate authorities for investigation by the Command Group. Such an event will not be managed under the auspices of the MTF PSM regardless of the SAC score. (See paragraph 3-3e, above, for additional information.)

(e) Some events fall within the definition of both an adverse event and an intentional unsafe act. For example, an infant abduction would be both a crime and a JCAHO-reportable sentinel event that requires an RCA. In cases that appear to be an adverse event and an intentional unsafe act, primary authority and responsibility for dealing with the event belongs to the Commander and RM; this event is beyond the scope of the PSP. The PSM will coordinate a review of the systems and processes implicated in the actual or potential intentional unsafe act, to include conducting an RCA, if applicable, but will defer to the separate command investigation with respect to the culpability of any person involved in the event.

(3) *External reporting requirements*. All incidents meeting the definition of a sentinel event must be reported to MEDCOM, and those that meet the criteria for review by JCAHO will be appropriately reported to that organization. External reporting of the PS event is the responsibility of the Commander (or his or her designee) and includes notification of—

(a) *The MEDCOM PSC*. All incidents meeting the definition of a sentinel event and those that result in serious patient harm must be reported to the MEDCOM PSC within 72 hours of identification of the event. MEDCOM Form 732-R (Sentinel Event Report Worksheet), which is available in FormFlow, will be completed and transmitted by facsimile, electronic mail, or other electronic means of communication to the MEDCOM PSC. The MEDDAC will also electronically notify the RM of the occurrence of a sentinel event.

(b) *JCAHO*. All sentinel events that are subject to review by JCAHO, as listed in paragraph 4-4b(3), below, must be reported to JCAHO within five working days of the identification of the event. Appropriate documentation, as required in current JCAHO guidance at the following internet address will be completed and forwarded by facsimile transmission or commercial overnight delivery service to the JCAHO Office of Quality Monitoring, 1 Renaissance Boulevard, Oakbrook Terrace, IL 60181 (http://www.jcaho.org/accredited+organizations/health+care+network/sentinel+events/forms+and+tools/index.htm). No patient or caregiver identifiers will be used when reporting a sentinel event to JCAHO.

4-5. PS event classification

The PSM and/or Risk Manager is responsible for reviewing and categorizing all reported PS events according to current DoD guidance, which is contained in this regulation. SAC methodology categorizes each PS event using a l to 3 risk scoring scale as follows: 1 = low risk, 2 = moderate risk, and 3 = high risk. SAC score methodology identifies the level of PS event analysis appropriate for the incident being considered.

a. SAC scoring of each PS event is based on the severity of the incident and its probability of recurrence. While there is some degree of subjectivity and individual judgment involved in this classification methodology, it provides organizations a standardized process for prioritizing actions and applying facility resources where there is the greatest opportunity to improve safety.

b. It is MEDDAC policy to proactively evaluate and analyze any event, regardless of SAC score, that presents significant potential for future recurrence. Close calls generally occur more frequently than actual adverse events. Thus, proactive analysis of a close call provides an ideal opportunity to implement system or process improvements without having to experience an actual adverse event. With a close call/near miss, the decision to charter a formal RCAT is at the discretion of the MTF leadership.

(1) *SAC 1 and SAC 2 no-harm events*. All SAC 1 and SAC 2 close calls and/or actual PS events with no harm to the patient will be entered into the PS/RM database. Monthly review and analysis for trends and/or process improvement opportunities will be conducted. The PST will review, prioritize, monitor and track the effectiveness of all actions implemented.

(2) *SAC 2 patient harm events*. All SAC 2 events that result in harm to the patient will be reviewed by the PSM and the Risk Manager or designee, to identify the appropriate level of event analysis warranted. If necessary, the MEDCOM PSC will be consulted to assist in identifying the best course of action for SAC 2 event management.

(3) *SAC 3 events*. Sentinel events that are subject to review by JCAHO and all other SAC 3 actual PS events require a route cause analysis. For close calls/near misses with a potential SAC 3

score, an RCAT will be chartered to provide the opportunity for organizational improvement. Sentinel events that are subject to review by JCAHO include—

(a) All events resulting in an unanticipated death or major permanent loss of function (unrelated to the natural course of the patient's illness or underlying condition).

(b) Infant abduction.

(c) Rape of a patient.

(d) Hemolytic transfusion reaction involving administration of blood or blood products having major blood group incompatibilities.

(e) Surgery on the wrong patient, wrong body part, and/or the wrong site.

4-6. PS event analysis

Event analysis assists in the discovery of the root causes and/or contributing factors associated with the PS event. Tracking and trending of data elements allows the PSM to identify familiar trends or circumstances so that system or process issues can be identified and improved. Levels of analysis include an aggregate review analysis and an RCA.

a. *Aggregate review analysis*. Aggregate review analysis consists of examining data elements for common trends or patterns within the group. The use of an aggregated review serves two important purposes. It allows wider applicability of the analyses (that is, trends or patterns that were not noticeable in an individual case analysis become more obvious as the number of similar cases increases). In addition, it more clearly defines specific data elements in a recurring problem and encourages prudent use of the time and expertise of the MTF staff associated with evaluation and corrective action.

(1) Falls and medication errors in which no serious patient injury resulted will be analyzed on a quarterly basis using an aggregate review analysis.

(2) Completed aggregate review analyses will be forwarded to the MEDCOM PSC at the following address: Commander, USAMEDCOM, ATTN: MCHO-Q, 2050 Worth Road, Fort Sam Houston, TX 78234-6010, within 45 days following the end of the quarter. A follow up after action report identifying the effectiveness of all system and process improvements will be forwarded to the MEDCOM PSC not later than six months following the submission of the aggregate review analysis.

b. *RCA*. An RCA must be conducted and an action plan completed for all actual SAC 3 PS events and those that meet the definition of a sentinel event. The Commander, in consultation with the DCCS, PSM and RMC, will designate and formally charter an RCAT to conduct a thorough and credible RCA. The RCAT will conduct the RCA according to current MEDCOM guidance to facilitate standardization of data element collection and event analysis across the Military Health System. The MEDDAC will use TapRoot® software and tools to conduct RCAs.

(1) RCA is the process for identifying the basic and/or contributing causal factors associated with PS events. The review is interdisciplinary and includes those who are closest to the process, and may or may not include those directly involved in the specific event. (Note: If not directly involved in the RCA, those individuals directly involved in the event will be consulted for event-related information.) The RCA focuses on systems and processes, not individual performance. The analysis asks "what" and "why" until all aspects of the process are reviewed and all contributing factors have been determined. It identifies changes that could be made in systems and processes to improve performance and to reduce the risk of adverse events, or the recurrence of close calls, with the ultimate goal of reducing and/or eliminating patient harm.

(2) If, in the course of conducting an RCA, it is determined that the PS event is the result

of an intentional unsafe act, deliberate gross negligence, deliberate reckless behavior, or possible criminal activity, the event will be reported to the appropriate command authorities for investigation. (See paragraph 3-3e, above.)

(3) The MTF Risk Manager and a legal advisor from the installation's Office of the Staff Judge Advocate (SJA) will be notified of all sentinel events and, if appropriate, either or both may participate in the RCA process.

c. *RCA action plan*. After the RCA has been completed, a detailed action plan will be developed to list the risk reduction strategies that the MTF intends to implement to prevent the recurrence of similar events. The action plan will address responsibilities for implementation, oversight, pilot testing (if appropriate), timelines, and the specific metrics to be employed in evaluating the effectiveness of the actions taken.

d. *RCA and action plan review*. The RCA and associated action plan for a sentinel event will be submitted to MEDCOM and JCAHO for review as follows:

(1) *MEDCOM*. A copy of the completed RCA and the action plan will be provided to the MEDCOM PSC within 45 calendar days of the MTF's discovery of the occurrence of a sentinel event. Commercial overnight delivery service is authorized for this purpose.

(2) *JCAHO*. If the sentinel event is subject to review by JCAHO, the MTF commander will select one of the two methods described below to deliver the RCA and action plan to JCAHO:

(a) Direct release of the RCA and the action plan to JCAHO using Certified Mail with a return receipt mail, or a commercial overnight delivery service.

(b) An on-site visit by a specially trained surveyor to review the RCA and the action plan. A request for on-site review must be received by JCAHO at least 15 days prior to the due date for completion of the RCA and the action plan.

e. *Action plan follow up review*. Six months following the RCA submission, a follow up after action report that addresses the effectiveness of the improvements implemented by the MTF will be forwarded to the MEDCOM PSC (Commander, USAMEDCOM, ATTN: MCHO-Q, 2050 Worth Road, Fort Sam Houston, TX 78234-6010). A copy will be provided to JCAHO, Office of Quality Monitoring, 1 Renaissance Boulevard, Oakbrook Terrace, IL 60181.

4-7. PS event communication

All MEDDAC staff are reminded that the data and information compiled as part of the PSP are quality assurance(QA)-information protected under 10 USC 1102 and must be marked "Quality Assurance protected document 10 USC 1102; Unauthorized Disclosure Carries $5000 Fine." The authority for review of this protected information by JCAHO and other specifically authorized external agencies appears in 10 USC 1102.

a. *The reporter of the PS event*. Staff members and supervisors who submit PS event reports will receive timely feedback on the actions being taken as a result of their reports. The nature of feedback to these individuals can range from a simple acknowledgement that the event is under consideration to providing information about the corrective action that is planned or has been accomplished. The date that such communication was completed will be annotated.

b. *Staff members involved in the PS event*. Any staff member who reports and/or who is directly involved in a PS event that caused patient harm will receive support and assistance from his or her supervisor to facilitate the staff member's professional and emotional needs, as related to the PS event. Management efforts and activities will focus on improving the systems and processes that may have contributed to the PS event rather than in disciplining those involved.

c. *Patient and family members affected by the event*. In cases involving an unanticipated outcome of care, a qualified health care provider will inform the patient/family. Prior to disclosure, the provider will consult with a member of the Executive Group, and, if required, the SJA. This information is provided as a matter of policy and does not affect any rights or obligations in legal or administrative proceedings. Under no circumstances will QA-protected information be released or provided to the patient/family.

(1) The commander, or designee, is responsible for ensuring that communication with the provider and the patient/family takes place. To ensure continuity, the initial disclosure of information and subsequent discussions with the patient/family should be handled, whenever possible, by the primary care manager or attending physician responsible for the patient's overall care. During the initial communication, and at subsequent planned discussions, at least one other MTF staff member should be present. For discussions anticipated to be complex or difficult, the patient/family may have another individual with them for support. The designated primary communicator will document in the patient's medical record what was communicated to the patient/family, the patient's/family member's response, and any other pertinent discussion.

(2) In most cases, facts surrounding the PS event that affect the patient can and should be disclosed to the patient/family by the provider.

(3) After the initial communication, any specific questions arising relative to disclosure of information associated with an unanticipated adverse outcome should be discussed with the Risk Manager and DCCS, and, if appropriate, referred to SJA.

d. *Safe/best practices and lessons learned*. To facilitate a successful PSP, it is imperative that all levels of MEDDAC staff learn from PS-related incidents by being informed of the system and process contributing factors that resulted in patient harm.

(1) The PSM will provide feedback to all levels of MEDDAC staff on reported PS events and lessons learned. These include PS improvement strategies and best/safe practices to be implemented at the unit or clinic level to prevent recurrence of similar events in the future.

(2) The MEDCOM PSC and Armed Forces Institute of Pathology (AFIP) will identify trends and opportunities for improvement, to include safe/best practices and implementation strategies identified through corporate and Military Healthcare System PS event analysis. This information will be distributed using the MEDCOM PSC and AFIP web sites and other appropriate communi-cation mechanisms.

(3) The PSM will also receive regular electronic and telephonic feedback and support from the MEDCOM PSC regarding sentinel events, RCAs, aggregate analyses, and the development and evaluation of RCA action plans.

4-8. PS education and training

a. *MEDDAC staff*. All members of the staff (that is all assigned and attached military, DA civilians, contractor employees, visiting providers, and Red Cross volunteers) will receive PS education and training during their initial orientations and on an annual basis via Computer-based Annual Training. PS-related topics include but are not limited to:

(1) An overview of the AMEDD PSP and MTF program execution.

(2) Roles and responsibilities in reporting PS events.

(3) Patient education requirements.

(4) Effective communication and teamwork strategies.

b. *Patients and family members*. Health care beneficiaries and family members will receive

education about their role in helping to facilitate the safe delivery of health care. Topics will include general information about the PSP and the ways beneficiaries and their family members can effectively participate in PS.

c. *RCAT members*. Personnel selected to serve on an RCAT will receive "just-in-time" training that includes RCAT process guidance and team rules, effective interview techniques, and the appropriate use of RCA tools (that is, flow charts and cause and effect diagrams). Formally trained RCAT facilitators will provide this training and assist the team in the process.

4-9. PSP metrics

The effectiveness of the PSP will be evaluated at all levels using standardized metrics. The current PSP metrics are listed in appendix C. These metrics, as identified, relate to the PSP goals at the MEDDAC level for the first year of the program.

4-10. PS reporting

Internal and external reporting related to PSP includes—

a. *The MEDDAC Executive Committee*.

(1) Minutes and reports from the PST will be submitted through the MEDDAC Performance Improvement and Utilization Management Committee to the MEDDAC Executive Committee. These minutes and reports will summarize the results of MEDDAC organizational and high risk area assessments, PS events, as well as the progress on all action plans implemented as a result of PS event analyses. The PST will also provide recommendations to the Performance Improvement and Utilization Management Committee and Executive Committee for improvements to specific PS processes, PS initiatives, and other organizational changes, as appropriate.

(2) The annual Clinical Quality Management Program report submitted for review by the MEDDAC Executive Committee will include a PSP evaluation and summary of the MTF's organizational and high risk area assessments, PS events, as well as the progress on all action plans implemented as a result of PS event analyses. This report will be forwarded through the Commander to the MEDCOM PSC.

b. *The MEDCOM PSC*. A quarterly PS report, using the format provided by MEDCOM, will be forwarded electronically to the MEDCOM PSC. The report will include requested aggregate data and summarize the results of the MEDDAC PS event analysis, progress on action plans implemented, and the effectiveness of these actions, as appropriate. The report is due not later than 45 days after the end of each calendar quarter (that is, not later than 14 January, 15 May, 14 August and 14 November each year; however, if one of these dates falls on a Saturday, Sunday or federal holiday, the report will be due not later than the last duty day preceding that day).

Chapter 5
Confidentiality of Medical QA Information and Internal Controls

5-1. Confidentiality of medical QA information
As with other medical QA documents, any information, records, reports, minutes, and other documents directly associated with PS activities are protected under the provisions of 10 USC 1102. In discussing medical information with family members, MTF personnel will also comply with other applicable restrictions on nonconsensual disclosures, including those under the Privacy Act, 5 USC 552a; DoD 5400.11-R, and pertinent Service regulations. As a general rule under the Privacy Act, information regarding a patient's condition cannot be provided to others without the patient's consent. (Exceptions to this rule include subpoenas for medical records signed by judges and federal magistrates, requests from law enforcement agencies, and certain other official Government agencies.)

5-2. Internal controls
This regulation is not subject to the requirements of AR 11-2. It does not contain internal control provisions.

Appendix A
References

Section I
Required Publications

AR 40-61
Medical Logistics Policies and Procedures. (Cited in para 2-8.)

AR 40-68
Quality Assurance Administration. (Cited in para 3-3.)

MEDCOM Reg 40-41
The Patient Safety Program. (Cited in para 2-1.)

MEDDAC/DENTAC/VS Reg 15-1
U.S. Army Medical Department Activity, Fort George G. Meade (MEDDAC) Boards, Committees, Councils, Meetings, Support Groups, and Teams. (Cited in paras 2-2 and 2-7.)

MEDDAC Reg 40-32
Performance Improvement and Risk Management Plan. (Cited in para 3-3.)

Section II
Related Publications

AR 25-55
The Department of the Army Freedom of Information Act Program

AR 340-21
The Army Privacy Program

Comprehensive Accreditation Manual for Ambulatory Care, Joint Commission on Accreditation of Healthcare Organizations

DoD 5400.7-R
DOD Freedom of Information Act Program

DoD 5400.11-R
Department of Defense Privacy Program

DoD Directive 5400.11
DoD Privacy Program

DoD Directive 6040.37
Confidentiality of Medical Quality Assurance (QA) Records

DoD Instruction 6025.17
Military Health System Patient Safety Program

Institute of Medicine Report #1, To Err is Human: Building a Safer Health System. Washington, DC, National Academy Press, 1999

Institute of Medicine Report #2, Crossing the Quality Chasm for the 21st Century. Washington, DC, National Academy Press, 1999

MEDDAC Reg 40-30
Sentinel Event Reporting

29 Code of Federal Regulations 1960.70

United States Code, Title 10, Section 1102, Confidentiality of Medical Quality Assurance Records

Section III
Prescribed Forms

This section contains no entries.

Section IV
Referenced Forms

DA Form 4106
Quality Assurance/Risk Management Document

MEDCOM Form 732-R
Sentinel Event Report Worksheet

MEDDAC Form 756
"Near Miss" Report (for KACC)

MEDDAC Form 761
"Near Miss" Report (for Dunham USAHC)

MEDDAC Form 767
"Near Miss" Report (for Kirk USAHC)

Appendix B
Safety Assessment Code Matrix

B-1. Severity factors

a. Key factors for the severity categories are: extent of injury, length of stay, and level of care required for remedy. The four categories below apply to actual adverse events.

b. For actual close calls and adverse events, assign severity based on the patient's actual condition. Some incidents that occur may have such an overwhelming potential for a catastrophic event that an RCA will also be necessary, but that will be left to the discretion of the MTF.

Table B-1
Severity categories

Catastrophic	**Major**	**Moderate**	**Minor**
Patients with actual:	**Patients with actual:**	**Patients with actual:**	**Patients with actual:**
Death or major permanent loss of function (sensory, motor, physiologic, or intellectual) not related to the natural course of the patient's illness or underlying conditions (that is, acts of commission or omission). Suicide (inpatient or outpatient). Rape. Hemolytic transfusion reaction. Surgery or procedure on the wrong patient or wrong body part. Infant abduction or infant discharge to the wrong family. Death or major permanent loss of function that is a direct result of injuries sustained in a fall; or associated with an unauthorized departure from an around-the-clock treatment setting; or the result of an assault or other crime.	Permanent lessening of bodily functioning (sensory, motor, physiologic, or intellectual) not related to the natural course of the patient's illness or underlying conditions (that is, acts of commission or omission). Disfigurement. Surgical intervention required. Increased length of stay or level of care of 3 days or more.	Increased length of stay or higher level of care for less than 3 days.	No increased length of stay or increased level of care.

Continued on next page.

B-2. Probability Recurrence

a. Like the severity categories, the probability recurrences apply to actual adverse events and close calls. In order to assign a probability rating for an adverse event or close call, it is ideal to know how often it occurs *at your facility*. Sometimes, the data will be easily available because it is routinely tracked (for example, falls with injury and medication errors). Sometimes, getting a feel for the probability of events that are not routinely tracked will mean asking for a quick or informal opinion from staff most familiar with those events. Sometimes it will have to be your best educated guess.

(1) High: Likely to occur immediately or within a short period of time.
(2) Medium: Likely to occur several times in one to two years.
(3) Low: May happen greater than two years.

Table B-2
Severity Assessment Code matrix

PROBABILITY	SEVERITY			
	Catastrophic	Major	Moderate	Minor
High	3	3	2	1
Medium	3	2	1	1
Low	3	2	1	1

b. How the Severity Assessment Code matrix works. When you pair a severity category (table B-1) with a probability category (table B-2) for either an actual event or a close call, you get a ranked matrix score (3 = highest risk, 2 = intermediate risk, 1 = lowest risk). These ranks, or Safety Assessment Codes (SAC) can then be used for doing comparative analysis, and, for deciding who needs to be notified about the event.

Notes:
1. All known reporters of events, regardless of SAC score (1, 2 or 3), will receive appropriate and timely feedback.
2. The Patient Safety Manager (or designee) will refer adverse events or close calls related solely to staff, visitors, equipment or facility damage to relevant facility experts or services on a timely basis, for assessment and resolution of those situations. (29 Code of Federal Regulations 1960.70 requires each federal agency to notify the Occupational Safety & Health Administration within eight hours of a work-related incident resulting in the death of an employee or the inpatient hospitalization of three or more employees.)
3. A quarterly aggregated analysis may be used for two types of events (this includes all actual events or close calls *other than actual SAC 3 events*, since all actual SAC 3 events require an individual RCA.) These two types are falls and medication errors. The use of aggregated analysis serves two important purposes. First, greater utility of the analysis (that is, trends or patterns not noticeable in individual case analysis are more likely to show up as the number of cases increases). Second, it makes wise use of the RCAT's time and expertise. Of course, the facility may elect to perform an individual RCA rather than an aggregated review on any adverse event or close call that they think merits that attention, regardless of the SAC score.

Appendix C
Patient Safety Program (PSP) Metrics

Qualitative standards will be established to evaluate the effectiveness of the PSP on an ongoing basis. The Patient Safety Team will define such metrics IAW baseline data obtained from the MEDCOM PSC or through local data analysis. As the program evolves and matures, its goals and objectives will change. Metrics used to measure program effectiveness will be modified to reflect these changes. As a minimum, the MEDDAC will implement the following during the first year of PSP implementation (that is, during fiscal year 2004) to measure the effectiveness of the program:

a. The MEDDAC's PSP is in place (that is, 100 percent compliant) as evidenced by the organization—

(1) Completing the MEDCOM PSP-identified PS risk assessment(s).

(2) Establishing a PS database.

(3) Conducting an aggregate review.

(4) Performing a prospective analysis and RCA.

b. The organization is actively transitioning to a culture of safety and openly discussing PS issues as evidenced by a median score in the climate survey reassessment of 10 percent over our baseline.

c. There is at least 50 percent close call/near miss reporting each quarter, as computed by comparing the number of close calls/near misses reported to the total number of PS events.

d. One system improvement and/or safe/best practice is identified, implemented, and monitored for effectiveness, using the Failure Mode and Effects Analysis (FMEA) model.

Glossary

Section I
Abbreviations

AFIP
Armed Forces Institute of Pathology

AMEDD
U.S. Army Medical Department

DA
Department of the Army

DCA
Deputy Commander for Administration

DCCS
Deputy Commander for Clinical Services

DCN
Deputy Commander for Nursing

DENTAC
U.S. Army Dental Activity, Fort George G. Meade

DoD
Department of Defense

IAW
in accordance with

IV
intravenous

JCAHO
Joint Commission on Accreditation of Healthcare Organizations

KACC
Kimbrough Ambulatory Care Center

MEDCOM
U.S. Army Medical Command

MEDDAC
U.S. Army Medical Department Activity, Fort George G. Meade

MTF
medical treatment facility

PCE
potentially compensable event

PS
patient safety

PSC
Patient Safety Center

PSM
Patient Safety Manager

PSP
Patient Safety Program

PST
Patient Safety Team

QA
quality assurance

RCA
route cause analysis

RCAT
Route Cause Analysis Team

RM
risk management

SAC
safety assessment code

SJA
Staff Judge Advocate

USAHC
U.S. Army health clinic

USC
United States Code

Section II
Terms

Action plan
The end product of an RCA that identifies the risk reduction strategies the organization intends to implement to prevent the recurrence of similar adverse events in the future.

Actual event
A situation or circumstance that did occur either with or without harm to the patient.

Adverse event
An occurrence or condition associated with the provision of health care or services that may or may not result in harm to the patient. Adverse events may be due to acts of commission or omission. Incidents

such as patient falls or improper administration of medications are also considered adverse events even if there is no harm or permanent effect on the patient.

Aggregate
To combine standardized data and information collected over time.

Aggregate review
The process of analyzing recurring incidents, events or close calls (near misses) for trends and patterns. This information is utilized by the organization for process improvement interventions.

Close call
An event or situation that could have resulted in harm to a patient, but did not, either by chance or through timely intervention. The event was identified and resolved before reaching the patient. Such events have also been referred to as "near miss" incidents. Because close calls generally occur more frequently than actual adverse events, proactive analysis of close calls provides tangible opportunity to improve the system without having to experience an actual adverse event. Leaders should emphasize the value of close calls and encourage and acknowledge staff for reporting these opportunities for improvement.

Contributing factor
An additional reason, not necessarily the most basic reason, for an event to be less than ideal, as planned, or as expected. A contributing factor may apply to an individual, a systems operation, or the to the entire organization.

Data
Material facts or clinical observations that have not been interpreted.

Evaluation
Analysis of collected, compiled and organized data pertaining to important aspects of care. Data are compared with predetermined, clinically valid criteria; variations from criteria are determined to be acceptable or unacceptable; and problems or opportunities to improve care are identified.

Gross negligence
See Reckless conduct.

Intentional unsafe act
Any alleged or suspected deliberate act or omission by a provider, staff member, contractor, trainee or volunteer pertaining to a patient that involves a criminal act, a purposefully unsafe act, patient abuse, or an event caused or affected by drug or alcohol abuse. Intentional unsafe acts are matters for law enforcement, the military or civil service disciplinary systems, or an administrative investigation, and are not within the definition of an adverse event.

Near miss
An event or situation that could have resulted in harm to a patient but did not, either by chance or through timely intervention. The event was identified and resolved before reaching the patient. Such events have also been referred to as "close call" incidents.

Patient safety event
An incident or error that occurred (an actual event), or almost occurred (a close call/ near miss), that caused or had the potential for causing harm to a patient.

Quality improvement
An approach to the continuous study and improvement of the processes of providing health care services to meet the needs of individuals and others. Synonyms include continuous quality improvement, continuous improvement, organization-wide performance improvement, and total quality management.

Rape
Sexual intercourse by a person, executed by force and without consent of the victim. It may be committed on a victim of any age. Any penetration, however slight, is sufficient to complete the offense. The Uniform Code of Military Justice, Article 120, states, "Any per-

son subject to this chapter who commits an act of sexual intercourse by force or without consent, is guilty of rape."

Reckless conduct
Involves conscious disregard of risk. Also referred to as gross negligence. Reckless conduct differs from "negligent conduct" in intent. Negligence is the failure to recognize a risk that should have been recognized, while reckless conduct is a conscious disregard of a known risk. NOTE: The legal definitions may vary slightly.

Risk assessment
A method used to proactively evaluate the probability of a patient safety event in order to minimize the risk of the event actually occurring.

Risk management
Clinical and administrative activities that organizations undertake to identify, evaluate and reduce the risk of injury to patients, staff and visitors, and the risk of financial loss to the organization. It involves identification of risk potential, prevention of risk exposure, and the management of real or potential adverse incidents and medical malpractice claims.

Root cause
The most basic reason that a situation did not turn out ideally, as planned or as expected.

Root cause analysis
A process for identifying the basic or contributing causal factor(s) associated with an adverse event or close call. The review is interdisciplinary and includes those who are closest to the process. It focuses on systems and processes, not individual performance. The analysis asks "what" and "why" until all aspects of the process are reviewed, and all contributing factors have been determined. It identifies changes that could be made in systems and processes to improve performance and reduce the risk of adverse events or recurrence of close calls.

Root Cause Analysis Team (RCAT)
The group identified by the MTF commander to develop the route cause analysis and action plan. The RCAT should include leaders of performance im-provement/quality management, risk management, nursing and patient care services, the medical staff, the department head or supervisor of the area in which the event occurred, administrative staff (such as the Deputy Commander for Administration, Risk Manager, and Safety Officer), a Staff Judge Advocate representative, and others, as necessary, depending on the event. RCAT members will be trained and knowledgeable in the sentinel event process.

Safety assessment code (SAC) matrix
A risk assessment tool that considers the severity of an adverse or near miss event together with the probability of the event's recurrence. The score, or SAC, assigned to the event determines the type of action that should be taken to address the event (that is, a route cause analysis, intense analysis, or no action). See appendix B.

Sentinel event
An unexpected occurrence involving death or serious physical or psychological injury, or the risk thereof, that is not related to the natural course of the patient's illness or underlying condition. Serious physical injury specifically includes loss of limb or function. The phrase, "or the risk thereof," includes any process variation for which a recurrence would carry a significant chance of a serious adverse outcome. Such events are called "sentinel" because they signal the need for immediate investigation and proactive response on the part of the organization.